

Notice of Allowability

Application No.

10/800,328

Examiner

Zachary C. Tucker

Applicant(s)

BRIGHT ET AL.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to ____.
2. ☒ The allowed claim(s) is/are 36-39.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 15Nov04
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date ____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other ____.

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

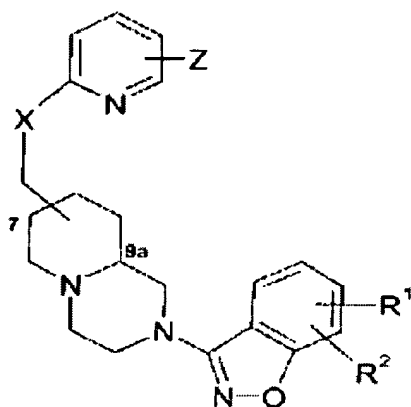
Authorization for this examiner's amendment was given in a telephone conversation with applicants' counsel, Mary J. Hosley on 17 February 2006, on the condition that applicant reserves the right to file a subsequent application on any cancelled subject matter.

IN THE SPECIFICATION –

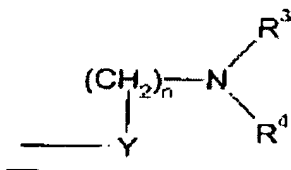
The abstract of the disclosure has been replaced with the following amended abstract:

Abstract of the Disclosure

An aminomethylpyridyloxymethyl/benzisoxazole substituted azabicyclic compound of formula I, a pharmaceutical composition comprising same, and a method of treating one or more CNS or other disorders, including concurrent treatment of disorders such as schizophrenia and depression, wherein formula I is



or a pharmaceutically acceptable salt thereof, wherein Z is

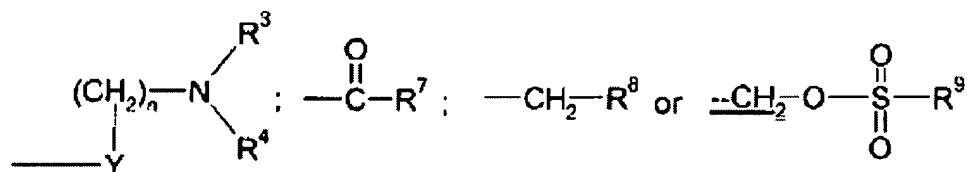


wherein Y is methylene; X is oxygen; n is 0; R¹ and R² are each hydrogen or halogen; and R³ and R⁴ together with the nitrogen atom to which they are attached form i) a saturated non-aromatic 3 to 7 membered monocyclic ring, said ring i) being unsubstituted or substituted with one or more (C₁-C₄)alkyl, (C₁-C₄)alkoxy(C₁-C₄)alkyl, or hydroxy groups.

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Please replace the paragraph at page 2, lines 19-23 with the following:

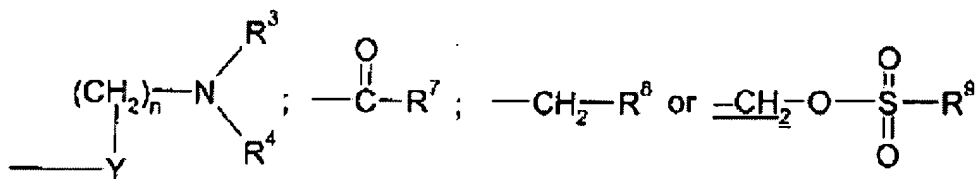
or the (R) or (S) enantiomer thereof, or the *cis* or *trans* isomer thereof, or a pharmaceutically acceptable salt, solvate or prodrug thereof or of any of the foregoing, wherein m is 0 or 1; Z is



wherein R⁷ is hydrogen or (C₁-C₃)alkoxy; R⁸ is hydrogen, hydroxy, or (C₁-C₃)alkoxy; and R⁹ is (C₁-C₃)alkyl;

Please replace the paragraph at Page 3, line 21 spanning to page 4, line 3 with the following:

or the (R) or (S) enantiomer thereof, or the *cis* or *trans* isomer thereof, or a pharmaceutically acceptable salt, solvate or prodrug thereof or of any of the foregoing, wherein Z is



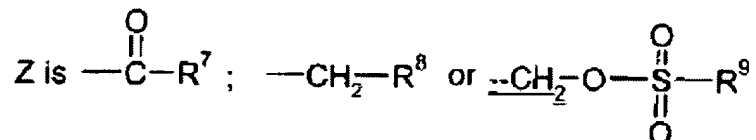
wherein R⁷ is hydrogen or (C₁-C₃)alkoxy; R⁸ is hydrogen, hydroxy, or (C₁-C₃)alkoxy; and R⁹ is (C₁-C₃)alkyl;

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Please replace the paragraph at page 14, lines 16-20 with the following:

as a racemate, or the (R) and (S) enantiomers thereof, or the *cis* and *trans* isomers thereof, wherein X is oxygen or NR, wherein R is hydrogen or (C₁-C₆)alkyl;

R¹ and R² are each independently as hereinbefore defined and



wherein R⁷ is hydrogen or (C₁-C₃)alkoxy; R⁸ is hydrogen, hydroxy, or (C₁-C₃)alkoxy; and R⁹ is (C₁-C₃)alkyl.

IN THE CLAIMS –

In claim 36, line 9, the phrase “or solvate” has been deleted.

In claim 38, line 9 (of page 9 of the Preliminary Amendment filed 27 September 2005), the phrase “or solvate” has been deleted.

In claim 38, immediately before the period at the end of the claim, the phrase –in combination with a pharmaceutically acceptable carrier—has been inserted.

End of amendments

Allowable Subject Matter

Claims 36-39 are allowed.

The following is an examiner's statement of reasons for allowance:

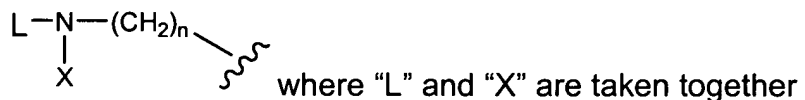
Compounds according to instant claims 36 and 37, and compositions comprising the compounds, according to claims 38 and 39, are not known from the prior art, nor does any suggestion or teaching found therein render said compounds or compositions obvious. As the closest relevant prior art, the examiner would cite the following patents:

US 5,157,034 (Bright et al),

US 5,565,453 (Bright et al) and

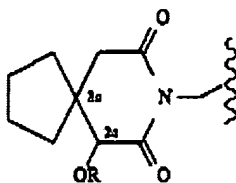
US 6,525,048 (Bright),

each of which are cited in the Information Disclosure Statement filed 15 November 2004. '048 represents the disclosure most similar to the compounds according to the instant claims, but compounds of that invention lack the required pyridyloxymethyl group of the compounds according to the instant invention - the corresponding moiety is phenyloxymethyl. No suggestion is found in either to replace the phenyloxymethyl with the pyridyloxymethyl moiety found in the compounds according to the instant claims. '034 discloses compounds with the same saturated pyridopyrazine core, but the compounds disclosed therein comprise a group of the formula:



or separately, but cannot form any aromatic heterocycle, and wherein also no oxygen atom is present. '453 discloses compounds comprising the saturated pyridopyrazine core, but those compounds, instead of the pyridyloxymethyl moiety possess a group having this structure:

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The attached Examiner's Amendment deletes the recitation of "or solvates" from claims 36 and 38; and adds a recitation of a pharmaceutically acceptable carrier to the composition according to claim 38. Also, a generic structure has been added to the abstract.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

All Post-Allowance Correspondence concerning this application must be mailed to:

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Or you can fax them to the Office of Patent Publications at 703-872-9306, in order to expedite the handling of such correspondence as amendments under 37 CFR 1.312; information disclosure statements, and formal drawings. Sending Post-Allowance papers to Technology Center 1600 will only cause delays in matching papers with the case.

For information concerning status of correspondence sent after receipt of the Notice of Allowance, please contact the Correspondence Branch at (703) 305-8027. The Notice of Allowance also has an insert containing contact information on other items, including Issue Fees, receipt of formal drawings and the status of the application.
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JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600